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SUMMARY OF SAFETY AND EFFECTIVENESS

I. SUBMITTER

Name and Address: American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, MN 55343 USA

Establishment Registration Number: 2183959 OCT 29 1997

Contact Person: John M. Otto

Date of Summary Preparation: July 18, 1997

II. DEVICE NAME

Device Common or Usual Name: Artificial Urinary Sphincter

Device Trade Name: AMS Sphincter 800™ Urinary Prosthesis

III. PREDICATE DEVICE

Implanted Mechanical/Hydraulic Urinary Continence Device

IV. DEVICE DESCRIPTION

The AMS Sphincter 800™ Urinary Prosthesis is a three component system designed to maintain continence by applying minimal pressure around the circumference of the bladder neck or bulbous urethra. The device is totally implanted.

The device is made of solid silicone elastomer and consists of a control pump, a pressure regulating balloon, and an occlusive cuff. The pump is implanted in subcutaneous tissue of the scrotum or labia. The pressure regulating balloon is inserted into the prevesical space. The cuff is totally implanted around the bulbous urethra or bladder neck. Fluid in the cuff exerts an occlusive force on the urethra. By depressing the control pump bulb, fluid moves from the cuff, back to the pressure regulating balloon, allowing the patient to void. Fluid travels slowly back to the cuff which will restore continence.

American Medical Systems proposes to modify the tubing socket of the valve block that is part of the control pump. A new design of the tubing socket, with a ½ inch long, tapered strain relief is proposed to replace the old ¼ inch long strain relief. The modification is being made to improve the performance of the device.

V. INDICATION FOR USE

The AMS Sphincter 800™ Urinary Prosthesis is an implantable, fluid-filled, solid silicone elastomer device used to treat urinary incontinence caused by Intrinsic Sphincter Deficiency (ISD). The AMS Sphincter 800™ Urinary Prosthesis is implanted in men, women, and children.

VI. COMPARISON TO PREDICATE DEVICE

The AMS Sphincter 800™ Urinary Prosthesis with the modified tubing socket is substantially equivalent to the current AMS Sphincter 800™ Urinary Prosthesis in commercial distribution.

a. Intended Use

The AMS Sphincter 800™ Urinary Prosthesis with the modified tubing socket has the same intended use as the standard AMS Sphincter 800™ Urinary Prosthesis. This product is an implantable, fluid-filled, solid silicone elastomer device used to treat urinary incontinence caused by Intrinsic Sphincter Deficiency (ISD). The AMS Sphincter 800™ Urinary Prosthesis is implanted in men, women, and children.

b. Principles of Operation

In both the current and modified device, the patient squeezes the pump mechanism, located in the scrotum or labium, several times to move fluid from the cuff to the pressure regulating balloon located in the abdomen. Fluid gradually flows back into the cuff, restoring continence after a few minutes. Pressure in the cuff is maintained at a nearly constant level by a pressure regulating balloon.

c. Device Performance

The AMS Sphincter 800™ Urinary Prosthesis with the modified tubing socket is comparable with respect to intended use and technological characteristics to the AMS Sphincter 800™ Urinary Prosthesis which is in commercial distribution in the United States.

d. Bench Testing

American Medical Systems has provided descriptive data on the test plan and test results for the modified Sphincter 800 pump. These data support that the function and characteristics of the device are suitable for its intended use.

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In summary, American Medical Systems has provided information within the 510(k) Premarket Notification to indicate that the Sphincter 800™ Urinary Prosthesis with the modified tubing socket is safe and effective for its intended use in the treatment of urinary incontinence. Additionally, the modified Sphincter 800 pump has been shown to be comparable in terms of intended use and technological characteristics to the current Sphincter 800 pump that is in commercial distribution. The data and information provided within this 510(k) Premarket Notification adequately support that the AMS Sphincter 800™ Urinary Prosthesis with the modified tubing socket is substantially equivalent to the AMS Sphincter 800™ Urinary Prosthesis that is currently in commercial distribution.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 1997

Mr. John M. Otto
Senior Regulatory Affairs Associate
American Medical Systems, Inc.
Pfizer Hospital Products Group
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K972707
AMS Sphincter 800™ Urinary Prosthesis
Dated: October 21, 1997
Received: October 23, 1997
Regulatory class: III
21 CFR §876.5280/Product code: 78 EZY

Dear Mr. Otto:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if Known): K972707

Device Name: AMS Sphincter 800™ Urinary Sphincter

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Natting
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972707

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The Counter Use ☐

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